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## EUROPEAN PATENT APPLICATION

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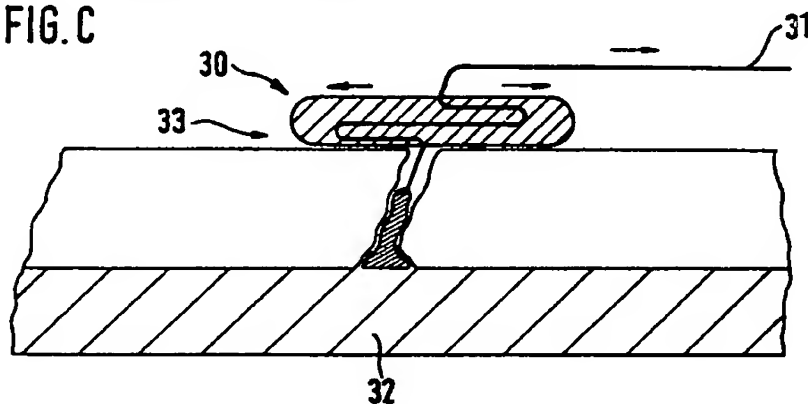
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### Tension holder e.g. for vascular suture or plug device

The invention relates to a device with a mechanism to exert tension upon a string like element such as suture. The device has its major extension in the plane in which it is positioned and its minor extension along axis of tension exertion. Said tension mechanism allows lateral or spiral displacement of the string like

element, wherein the tensile mechanism has elastic (springy) property, and said mechanism is not substantially extending above the upper surface of the device. This device is particularly used in association with a hemostatic plug to which a string is attached.

FIG. C



tion

und:

With the proliferative use of percutaneous vas-  
interventions such as Percutaneous Transluminal  
y Angioplasty (PTCA), angioplasty in other than  
/ vessels (PTA), stenting, atherectomy, laser  
ain other minimally invasive procedures in car-  
angiology, cardiosurgery, radiology and surgery  
as other disciplines, a need for percutaneous  
devices of the operative entry site or vascular  
site has been established.

In particular after percutaneous vascular pro-  
such as PTCA and PTA a method of nonsurgi-  
re with or without a suture of the puncture site  
ven helpful in reducing bleeding complications,  
j the time necessary to mechanically or manu-  
press the vascular access site until hemostasis  
ed and recucing the time to patient discharge.  
r closure devices may reduce hospitalization  
d may be helpful in performing catheter guided  
reous procedures on a outpatient basis.

However there are still problems associated  
sure devices, which need to be addressed. Clo-  
vices that use sutures applied by needles are  
ys reliable and may need an additional means  
stasis such as a collagen or other plug on top of  
ular puncture site or in the puncture channel.  
g, however, carries the risk of getting dislodged  
embolizing into the circulation. This may be a  
r risk if repeat procedures have to be carried  
gh the same puncture channel within hours or a  
s after the initial procedure. Therefore, closure  
that employ plugs should be associated with a  
mechanism to hold the plug in place. Also, often,  
led that sutures are being kept under tension for  
me to safely achieve hemostasis. Therefore,  
closure devices featuring needles and sutures  
as vascular closure devices employing puncture  
ys need a mechansim to hold the suture under  
and the plug safely in place in order to improve  
and safety of the closure device. This applies  
closure devices used in other minimally invasive  
rative procedures where (percutaneous) closure  
may be of advantage. It is irrelevant for the use-  
of such tension holding device or plug securing  
whether the plug is located totally or partially in  
ular lumen or totally or partially in the puncture  
perative access site channel.

Major feature of such closure device and tension  
nd / or plug securing device is, that such device  
t prohibit manual compression upon the puncture  
eeded in case of failure of any of the closure

Some of the closure devices are of such a con-  
n, that no additional manual or any other  
ical compression is possible, since the device is  
ig significantly above the percutaneous access

site (puncture site) level. Mechanical compression would  
critically damage the device and/or inflict trauma to the  
patient. One solution may be the removal of the part of  
the device that is extending significantly above the  
access site level (usually the tension hlding part of the  
device). However, this carries among other risks e.g.the  
risk of loosing the plug into the circulation.

[0004] It has been found, that the present invention is  
solving such shortcomings by describing a closure  
device with a tension hlding part that is not significantly  
extending above the access site level and that permits  
application of manual / other mechanical pressure with-  
out the risk of reducing the safety and function of the  
device and without the risk of traumatizing the accesss  
site and its surrounding tissue (percutaneous puncture  
site area)

Prior art:

[0005] The vascular puncture site sealing device using  
a collagen plug commercially exploited under the trade  
name VASOSEAL by Datascope Corp, USA; the com-  
bined plug and intravascular anchor device, commercially  
exploited under the trade name ANGIO-SEAL by Sher-  
wood Davies & Geck, USA and the suture devices by  
Perclose Inc, USA. (including Int application Nr WO  
95/13021 and WO 94/13211)

Other prior art includes the device description by  
Howard Taymor-Luria, USA (US patent 5415657) and by  
Gene Myers (US patent 5486195); and the international  
patent applications by David Hathaway et al (Int publica-  
tion Nr WO 94/08516). These description deal with the  
use of closure devices and do not describe a suture ten-  
sion device and/or plug securing device. However, in  
particular with use of the ANGIO SEAL device, a plug  
securing and suture tension holding device that con-  
forms to the practical needs is a necessity.

[0006] Any description of the present invention will  
focus on vascular closure devices as they are primarily  
used after vascular catheterization procedures, yet the  
description is not limited to such uses; any other use  
such as after endoscopic procedures, in gynecology,  
gastroenerology are other operative or minimally inva-  
sive procedures may also represent areas of use. "A"  
always means also more than one.

Description of invention:

[0007] Once a collagen plug is placed within a punc-  
ture site channel and associated (attached) with a string  
(suture) or a plug or anchor is placed intravascularly  
and is pulled against the puncture site hole from outside  
via a string or suture or if a suture needs continued ten-  
sion for a period of time in order to bettr achieve hemo-  
stasis, a device that exerts continued traction upon such  
string or suture connection is often needed.

[0008] Such tension device will stay in place for min-  
utes, hours or days and will exert the tension while

g positioned at the skin level of the patient at or  
 and the percutaneous access site (puncture site).  
 device needs an atraumatic configuration that min-  
 es trauma to the tissue it is resting/pushing on. This  
 particularly important, since by virtue of the tension  
 device is exerting the device will be pulled against  
 tissue. Also, the device needs to be flat, so that  
 hanical pressure (manual pressure) can be exerted  
 ed) on top of the device. So in the preferred config-  
 ons of the device its diameter in the axis of exertion  
 nsion (ie nearly perpendicular to the plane of the  
 ace of the skin) is less than its diameter in the axis  
 ie plane of the skin. In addition to the flat shape,  
 d or oval type configuration help to adapt the device  
 ie configurations of its respective positions, e.g. in  
 groin. The side of the device facing the skin may be  
 led for reduced trauma to the tissue and / or lined  
 a special optimally skin/tissue compatible surface.

9] Another embodiment is a a open area of the  
 ce, i.e. a central or eccentrically located hole or a slit  
 are that accomodates the string or suture in such a  
 that the string or suture can be easily threaded  
 igh or into this opening. Once the suture or string  
 nent) upon which the tension is to be exerted is in  
 e, a fixation mechanism is activated in order to both  
 y fix the element in its desired distance from the  
 (one means to select the degree of tension) and  
 ate the tension mechsism located inside the flat  
 e.g. olive shaped device.

0] Commonly the device will be placed just at the  
 level with one hand, while the other hand is main-  
 ng slight tension on the string. Once the tension  
 fixation mechanism is activated, the device is exert-  
 ight tension and both hands can be released.

1] In one embodiment, the tension exerted by the  
 ce - which is dependent on the intial tension of the  
 g that had be held manually and the (elastic) prop-  
 and the thickness of the tissue between the plug or  
 suture - may be indicated by a simple gauge on the  
 ide of the device.

2] The mechanism its self consists of a spring  
 hanism that displaces the the string from its sraight  
 se to the side (Bajonett ähnlich) or rolls or partially  
 the string up until a tension limit inside the device.  
 position of the device can be changed; the tension  
 be determined by positioning (selecting the dis-  
 e to the skin surface) or by selecting a certain  
 ee of tension with the mechanism itself prior or  
 placement of the device.

ms

Device with a mechanism to exert tension upon a  
 string like element such as a suture, wherein the  
 device has its major extension in the plane on which  
 t is positioned and its minor extension along the the  
 axis of tension exertion (blunt, flat configuration),  
 said tension mechanism employing a primarily lat-

eral or spiral displacement of the string like ele-  
 ment, wherein the tensile mechanism has elastic  
 (springy) property, and said mechanism is not sub-  
 stantially extending above the upper surface of the  
 device, said tensile mechanism being active upon  
 activation from a non tensile to a tensile (functional)  
 state

2. Device of claim 1 wherein the device is flat oval  
 shaped (flat egg)

3. Device of claim one wherein the device is of a disc  
 like flat shape

4. Device of claim 1 wherein the device permits pres-  
 sure application on top of it without unacceptable  
 trauma to the underlying tissue

5. Device of claim 1, wherein the side of the device  
 facing the tissue (or in contact with the tissue) is of  
 soft material and/ or tissue compatible material

6. Device of claim 1 used in association with a hemo-  
 static plug to which a string is attached

7. Device of claim 1, wherein the strength of the ten-  
 sile mechanism can be preselected

8. Device of claim 1 wherein the actual degree of ten-  
 sion is indicated by a gauge

9. Device of claim 1 wherein the tensile mechanism  
 and fixation of the position of the device is activated  
 at the same time

10. Device of claim 1, wherein activation of the tensile  
 mechanism can be done by one hand

11. Device of claim 1, wherein the string to be extended  
 is inserted into the device through a central hole of  
 the device

12. Device of claim 1 wherein the string to be extended  
 is inserted into the device through a slit like opening

13. Device of claim 1 wherein the string to be extended  
 is leaving (exiting from the device) the device at  
 least on one side through a central or nearly central  
 hole or slit like hole

FIG. A  
Prior Art

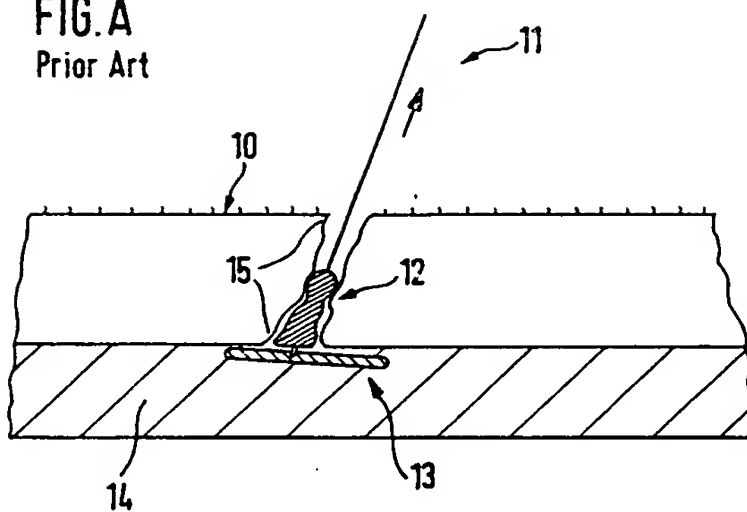


FIG. B  
Prior Art

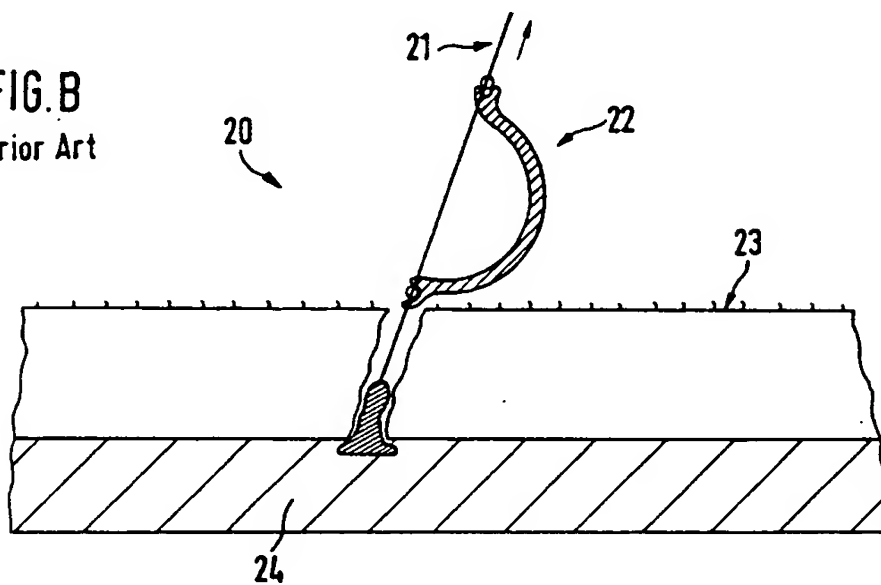


FIG. C

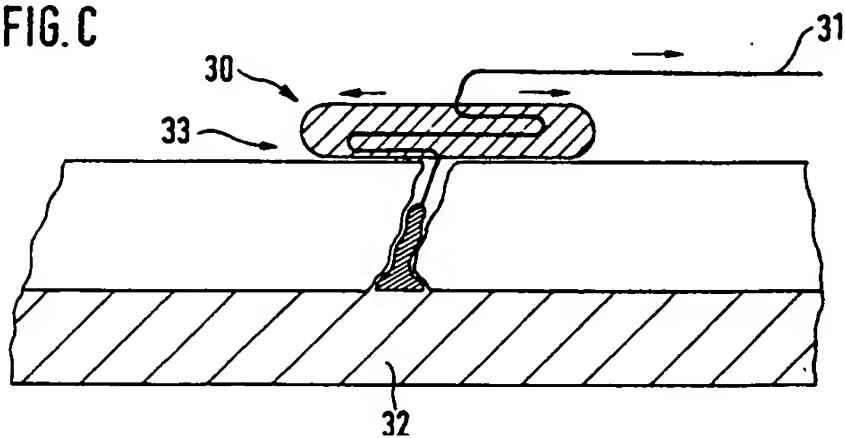


FIG. D

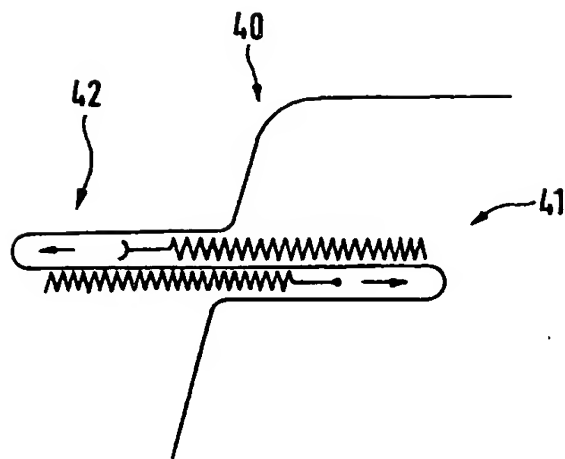


FIG. E<sub>1</sub>

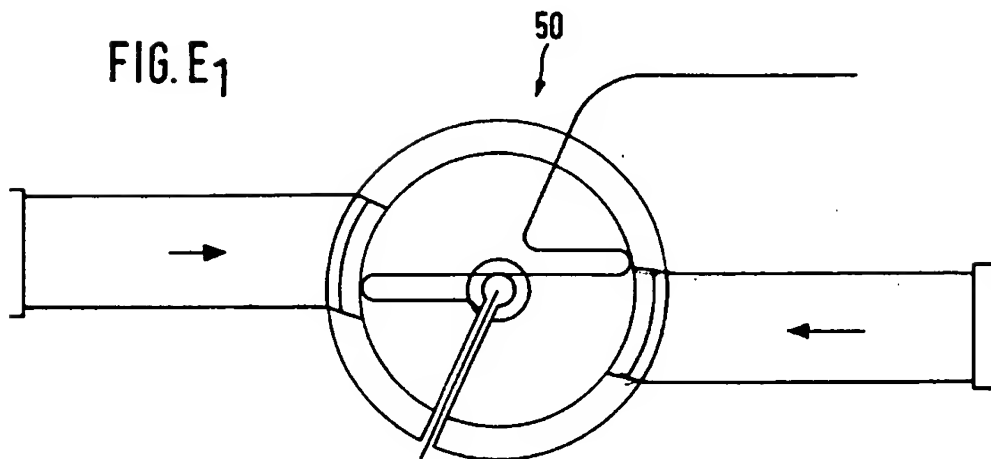
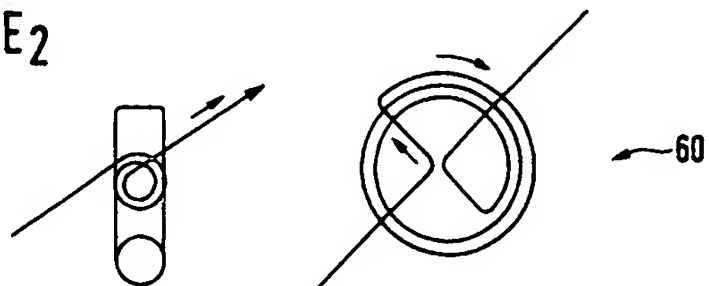


FIG. E<sub>2</sub>





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# EUROPEAN SEARCH REPORT

Application Number  
EP 97 11 2968

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	US 4 950 283 A (DZUBOW LEONARD M ET AL) * column 2, line 25 - line 32 *	1	A61B17/00
A	US 5 411 520 A (NASH JOHN ET AL) * column 14, line 58 - line 65 *	1,6	
A	WO 89 11301 A (KENSEY NASH CORP) * page 9, line 5 - line 18 *	1	
A	US 3 650 274 A (EDWARDS LEON C ET AL)		
A	US 4 750 492 A (JACOBS RANDALL W)		
A	DE 19 58 429 A (J. GAECKEL)		
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			A61B
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 25 November 1997	Examiner Gérard, B
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